

Effect of Endovascular Treatment Alone vs Intravenous Alteplase Plus Endovascular Treatment on Functional Independence in Patients With Acute Ischemic Stroke: The DEVT Randomized Clinical Trial.

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Abstract

Importance

For patients with large vessel occlusion strokes, it is unknown whether endovascular treatment alone compared with intravenous thrombolysis plus endovascular treatment (standard treatment) can achieve similar functional outcomes.

Objective

To investigate whether endovascular thrombectomy alone is noninferior to intravenous alteplase followed by endovascular thrombectomy for achieving functional independence at 90 days among patients with large vessel occlusion stroke.

Design, Setting, and Participants

Multicenter, randomized, noninferiority trial conducted at 33 stroke centers in China. Patients ($n = 234$) were 18 years or older with proximal anterior circulation intracranial occlusion strokes within 4.5 hours from symptoms onset and eligible for intravenous thrombolysis. Enrollment took place from May 20, 2018, to May 2, 2020. Patients were enrolled and followed up for 90 days (final follow-up was July 22, 2020).

Interventions

A total of 116 patients were randomized to the endovascular thrombectomy alone group and 118 patients to combined intravenous thrombolysis and endovascular thrombectomy group.

Main Outcomes and Measures

The primary end point was the proportion of patients achieving functional independence at 90 days (defined as score 0-2 on the modified Rankin Scale; range, 0 [no symptoms] to 6 [death]). The noninferiority margin was -10%.

Safety outcomes included the incidence of symptomatic intracerebral hemorrhage within 48 hours and 90-day mortality.

Results

The trial was stopped early because of efficacy when 234 of a planned 970 patients had undergone randomization. All 234 patients who were randomized (mean age, 68 years; 102 women [43.6%]) completed the trial. At the 90-day follow-up, 63 patients (54.3%) in the endovascular thrombectomy alone group vs 55 (46.6%) in the combined treatment group achieved functional independence at the 90-day follow-up (difference, 7.7%, 1-sided 97.5% CI, -5.1% to ∞) P for noninferiority = .003). No significant between-group differences were detected in symptomatic intracerebral hemorrhage (6.1% vs 6.8%; difference, -0.8%; 95% CI, -7.1% to 5.6%) and 90-day mortality (17.2% vs 17.8%; difference, -0.5%; 95% CI, -10.3% to 9.2%).

Conclusions and Relevance

Among patients with ischemic stroke due to proximal anterior circulation occlusion within 4.5 hours from onset, endovascular treatment alone, compared with intravenous alteplase plus endovascular treatment, met the prespecified statistical threshold for noninferiority for the outcome of 90-day functional independence. These findings should be interpreted in the context of the clinical acceptability of the selected noninferiority threshold.

Trial Registration

Chinese Clinical Trial Registry: ChiCTR-IOR-17013568.